

ATTACHMENT TO FDA 482

Resources for FDA Regulated Businesses

The U.S. Food and Drug Administration strives to protect, promote and enhance the health of the American people, while minimizing the regulatory burden on the industries it regulates. You have a right to disagree with any agency decision, action, or operation without fear of retaliation. You also have a right to be treated with appropriate courtesy and respect. If you are dissatisfied with any agency decision or action, you may appeal to the supervisor of the employee who made the decision or took the action. If the issue is not resolved at the first supervisor's level, you may request that the matter be reviewed at the next higher supervisory level. This process may continue through the agency's chain of command.

To resolve a problem with your company's interaction with FDA, or if you have questions or concerns about FDA rules or procedures, we suggest that you first write or call your district office to explain your concerns. If you are not satisfied with the help provided by the district office, you may take your complaint or concern to the regional office. If that effort is not satisfactory, contact FDA's Office of the Chief Mediator and Ombudsman for further assistance and guidance.

Contact the District Office if you have a concern or question about an inspection, an import or export issue, or any other action taken by an FDA field representative. The District Office will provide you with the name and phone number of someone who will review the matter and provide assistance.

District	Telephone	District	Telephone
Atlanta	(404) 253-1169	Minneapolis	(612) 334-4100
Baltimore	(410) 779-5454	New England	(781) 596-7700
Chicago	(312) 353-5863	New Jersey	(973) 526-6000
Cincinnati	(513) 679-2700	New Orleans	(615) 781-5385
Dallas	(214) 253-5200	New York	(718) 340-7000
Denver	(303) 236-3017	Philadelphia	(215) 597-4390
Detroit	(313) 393-8100	San Francisco	(510) 337-6700
Florida	(407) 475-4700	San Juan	(787) 474-9500
Kansas City	(913) 752-2100	Seattle	(425) 486-8788
Los Angeles	(949) 608-2900	Southwest Import	(214) 253-5330

Contact the **Regional Office** for further help if you were not able to effectively resolve the issue with the assistance of the district office. Telephone numbers for the regional offices and a list of the states covered by each region are on the Internet at http://www.fda.gov/ora/hier/ora_field_names.txt.

Contact the **Office of the Chief Mediator and Ombudsman** at 301-827-3390 if you have been unsuccessful in resolving a problem at the district and regional levels. The office's home page is on the Internet at <http://www.fda.gov/oc/ombudsman/homepage.htm>.

The Small Business Administration also has an ombudsman. The **Small Business and Agriculture Regulatory Enforcement Ombudsman** and 10 Regional Fairness Boards receive comments from all kinds of small businesses about federal agency enforcement actions and annually evaluate the enforcement activities, rating each agency's responsiveness to small business. If you wish to comment on the enforcement actions of FDA, call 1-888-734-3247. The ombudsman's home page is on the Internet at <http://www.sba.gov/ombudsman>.

Small Business Guide to FDA

Internet at http://www.fda.gov/ora/fed_state/small_business/sb_guide/intro.html

Office of Regulatory Affairs (ORA)

Internet at <http://www.fda.gov/ora/>

Food and Drug Administration (FDA)

Internet at <http://www.fda.gov>